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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,114	08/02/2005	Francois-Xavier Jacques Berthet	B45314	4557

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EXAMINER	
ARCHIE, NINA	
ART UNIT	**PAPER NUMBER**
1645	

NOTIFICATION DATE	DELIVERY MODE
10/06/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/523,114	BERTHET ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,45-47 and 51-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,13-19,45-47 and 51-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/2/2005 and 4/11/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Specification

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

4. The information disclosure statement filed on 4/11/2008 and 2/2/2005 have been considered. An initialed copy is enclosed.

Election/Restrictions

5. Applicant's election with traverse of Group 1 (claims 1-19, 45-47, and 51-55) is acknowledged. The traversal is on the ground(s) that the Examiner alleges that the inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: (i) The technical feature of Group I is an immunogenic composition comprising an isolated transferrin binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria. (ii) The technical feature of Group I lacks an inventive step over Hermand et al WO 02/30458A1. (iii) Hermand et al teaches an immunogenic composition comprising an isolated transferrin binding protein (Tbp) and an isolated Hsf like protein from the same

or different Gram negative bacteria (see abstract and pgs. 1-5 and 13-16). Applicants respectfully traverse that the claimed subject matter lacks inventive step over Hermand et al. Applicants' representative has diligently reviewed Hermand et al. and cannot determine where it discloses an immunogenic composition comprising an isolated transferrin binding protein (Tbp) and an isolated Hsf like protein from the same or different Gram negative bacteria. Rather, Hermand et al. relates to adjuvant compositions that comprise a Yersinia adhesion protein which are suitable to be used in vaccines and further provides vaccines comprising the adjuvants and an antigen or an antigenic composition. (for example, abstract; page 1, lines 1-13; page 8, lines 17-21). This is not found persuasive.

The claims are drawn to an immunogenic composition comprising an isolated transferring binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria.

Hermand et al teach a vaccine composition comprising an antigen or antigenic composition from Gram Negative bacteria such as Neisseria. Hermand et al teach that Neisserial antigens Hsf-like and TbpA and TbpB (Examples and claim 9). The claims are drawn to an immunogenic composition comprising an isolated transferring binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria. Therefore the limitation have been met.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-12, 20-44, and 48-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species or Group, Group 1 (claims 9-12) or Group 2 (claims 20-44), Group 3 (claims 56-57), Group 4 (claims 58-59, 61-64, and 65), Group 5 (claims 60), Group 6 (claims 62-63), Group 6 (claim 66), Group 7 (claims 67-68), Group 8 (claims 67-68), Group 9 (claim 69), Group 10 (claim 70) there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement on 4/11/2008.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-8, 13-19, 45-47, 51-53, and 55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17, 19-45, 52-61, 93-113 of copending Application No. 10/523,117.

Claims 1-17, 19-45, 52-61, 93-113 of U.S. Application No. 10/523,117 teach to an immunogenic composition comprising an isolated transferring binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria.

Although the conflicting claims are not identical, they are not patentably distinct. The U.S. Application No. 10/523,117 recites the “immunogenic composition”. The species of the immunogenic composition anticipate the genus claims of any immunogenic composition.

Thus, claims 1-8, 13-19, 45-47, 51-53, and 55 encompassing the immunogenic composition in the present application are obvious over claims 1-17, 19-45, 52-61, 93-113of Application No. 10/523117.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-8, 13-19, 45, 47, and 51-55 are rejected under 35 U.S.C. 102(a) as being by Hermand et al WO 02/30458A1 April 18, 2002.

Claims 1-8, 13-19, 45, 47, and 51-55 are drawn to an immunogenic composition comprising an isolated transferring binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria.

Hermand et al teach a vaccine composition comprising an antigen or antigenic composition from Gram Negative bacteria such as Neisseria. Hermand et al teach that Neisserial antigens Hsf-like and TbpA and TbpB (Examples and claim 9). The claims are drawn to an immunogenic composition comprising an isolated transferring binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria. Hermand et al

teach adjuvant and vaccine preparations comprising 3D-MPL and CpG. Hermand et al teach that the vaccine formulations of the present invention contain an antigen or antigenic composition capable of eliciting an immune response against a human pathogen, which antigen or antigenic composition is derived from bacterial pathogens such as Neisseria spp, including N. gonorrhea and N. meningitidis (for example capsular polysaccharides and conjugates thereof, and transferrin-binding proteins, lactoferrin binding proteins (see claims and document in its entirety).

Hermand et al teach that examples of Neisserial antigens (including gonococcus and meningococcus, (particularly N. meningitidis B) Hsf-like, TbpA, TbpB, Tbp2. Hermand et al teach bacterial vaccines comprise antigens derived from Streptococcus spp, including S. pneumoniae, for example capsular polysaccharides and conjugates thereof, proteins having a Type II Signal sequence motif of LXXC (where X is any amino acid), and proteins having a Type I Signal sequence motif which are HSF-like. Hermand et al teach an adjuvant composition may further comprise a pharmaceutically acceptable carrier (see claims and document in its entirety).

Therefore the immunogenic composition of Hermand et al teach an immunogenic composition comprising an isolated transferrin binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria, in which the transferrin binding protein or fragment thereof and Hsf like protein or fragment thereof are from Neisseria, in which the transferrin binding protein or fragment thereof is derived from N. meningitidis, in which the Hsf like protein or fragment thereof is derived from N. meningitidis, in which the transferrin binding protein or fragment thereof is derived from N. meningitidis serogroup B, in which the Hsf like protein or fragment thereof is derived from N. meningitidis serogroup B, in which the transferrin binding protein or fragment thereof is derived from N. gonorrhoeae, in which the Hsf like protein or antigenic fragment thereof is derived from N. gonorrhoeae, in which the Hsf like protein is Hsf or an antigenic fragment thereof, in which the transferrin binding protein is TbpA or an antigenic fragment thereof, further comprising high molecular weight form TbpA or low molecular weight form TbpA or both high molecular weight form TbpA and low

molecular weight form TbpA, in which the Hsf like protein is Hsf or an antigenic fragment thereof, comprising antigenic fragments of Tbp and/or Hsf like protein capable of generating a protective response against Neisserial infection, comprising antigenic fragments of TbpA and/or Hsf, comprising a fusion protein of Tbp and Hsf like protein or antigenic fragments thereof, comprising a fusion protein comprising TbpA and Hsf or antigenic fragments thereof capable of generating a protective response against Neisserial infection, further comprising plain or conjugated bacterial capsular polysaccharide or oligosaccharide, wherein the capsular polysaccharide or oligosaccharide is derived from one or more bacteria selected from of Streptococcus pneumoniae, comprising an adjuvant, comprising aluminum salts, comprising 3D-MPL, comprising an adjuvant containing CpG. Hermand et al teach a vaccine comprising the immunogenic composition and a pharmaceutically acceptable excipient.

8. Claims 1-8, 13-19, 45-47, 51-55 are rejected under 35 U.S.C. 102(b) as being by Berthet et al WO/2001/009350 February 8, 2001.

Claims 1-8, 13-19, 45-47, 51-55 are drawn to an immunogenic composition comprising an isolated transferring binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria.

Berthet et al teach an immuno-protective and non-toxic Gram-negative bleb vaccine suitable for pediatric use. Examples of the Gram-negative strains from which the blebs are made are *N. meningitidis*. The blebs of the invention are improved by one or more genetic changes to the chromosome of the bacterium, including up-regulation of protective antigens, down-regulation of immunodominant non-protective antigens, and detoxification of the Lipid A moiety of LPS (see abstract).

Berthet et al teach bleb components produced conditionally and the expression of some genes coding for certain bleb components is carefully regulated. Berthet et al teach Neisserial bleb preparations one or more of the following genes (encoding protective antigens) are preferred for upregulation via processes b) and/or i) when

carried out on a Neisserial strain, including gonococcus, and meningococcus (particularly N. meningitidis B), Hsf-like, TbpA, TbpB. Berthet et al teach a genetically-engineered bleb preparation from a Gram-negative bacterial strain wherein the Gram-negative strain is Neisseria gonorrhoeae. Berthet et al teach the bleb preparation in the manufacture of a medicament for immunizing a human host against a disease caused by infection of one or more of the following: Neisseria meningitidis, Neisseria gonorrhoeae. Berthet et al teach a meningitis vaccine comprising the bleb preparation of one or more plain or conjugated pneumococcal capsular polysaccharides and a meningococcal vaccine comprising the bleb preparation of one or more plain or conjugated meningococcal capsular polysaccharides selected from the serotypes A, C, Y or W. Berthet et al teach bleb preparations of the present invention may be adjuvant in the vaccine formulation of the invention such as aluminum salt such as aluminum hydroxide gel (alum) or aluminum phosphate, and 3-de-O-acylated monophosphoryl lipid A (3D- MPL) together with an aluminum salt. Berthet et al teach that unmethylated CpG containing oligo nucleotides are suitable for use in the present invention (see claims and document in its entirety).

Therefore the immunogenic composition of Hermand et al teach an immunogenic composition comprising an isolated transferrin binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria, in which the transferrin binding protein or fragment thereof and Hsf like protein or fragment thereof are from Neisseria, in which the transferrin binding protein or fragment thereof is derived from N. meningitidis, in which the Hsf like protein or fragment thereof is derived from N. meningitidis, in which the transferrin binding protein or fragment thereof is derived from N. meningitidis serogroup B, in which the Hsf like protein or fragment thereof is derived from N. meningitidis serogroup B, in which the transferrin binding protein or fragment thereof is derived from N. gonorrhoeae, in which the Hsf like protein or antigenic fragment thereof is derived from N. gonorrhoeae, in which the Hsf like protein is Hsf or an antigenic fragment thereof, in which the transferrin binding protein is TbpA or an antigenic fragment thereof, further comprising high molecular weight form TbpA or low

molecular weight form TbpA or both high molecular weight form TbpA and low molecular weight form TbpA, in which the Hsf like protein is Hsf or an antigenic fragment thereof, comprising antigenic fragments of Tbp and/or Hsf like protein capable of generating a protective response against Neisserial infection, comprising antigenic fragments of TbpA and/or Hsf, comprising a fusion protein of Tbp and Hsf like protein or antigenic fragments thereof, comprising a fusion protein comprising TbpA and Hsf or antigenic fragments thereof capable of generating a protective response against Neisserial infection, further comprising plain or conjugated bacterial capsular polysaccharide or oligosaccharide, wherein the capsular polysaccharide or oligosaccharide is derived from one or more bacteria selected from of Streptococcus pneumoniae. Berthet et al teach a vaccine comprising the immunogenic composition and a pharmaceutically acceptable excipient, comprising two or more bacterial capsular polysaccharides or oligosaccharides conjugated to transferrin binding protein or Hsf like proteins or both, comprising an adjuvant, comprising aluminum salts, comprising 3D-MPL, comprising an adjuvant containing CpG.

Citation of Relevant Art

9. Robinson et al US Application 2003/0215469 Date November 2003 teach composition is provided comprising N. meningitidis outer membrane vesicles, wherein said outer membrane vesicles are enriched with at least one antigenic component. The composition is suitable for use in vaccines and for treatment of infection, particularly meningococcal infection, demonstrating a broad spectrum of protection. A number of preferred antigenic components are described and include antigenic proteins and proteoglycans derived from N. meningitidis.

Status of the Claims

10. No claims are allowed.

Claims 1-8, 13-19, 45-47, 51-55 are rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0898 and Robert Mondesi at 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina Archie
Examiner
Art Unit 1645

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